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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/686,891

10/15/2003

Amir J. Tehrani

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EXAMINER

ALTER, ALYSSA M

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

06/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/686,891	Applicant(s) TEHRANI, AMIR J.	
	Examiner ALYSSA M. ALTER	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 123-127, 141, 142 and 149-158 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 123-127, 141, 142 and 149-158 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/6/07 & 10/29/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group IV in the reply filed on May 30, 2007 is acknowledged.

Response to Arguments

Applicant's arguments with respect to claims 123-127, 141-142 and 149-158 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 123-127, 141-142 and 149-158 are rejected under 35 U.S.C. 102(b) as being anticipated by Testerman et al. (US 5,522,862). Testerman et al. discloses a typical respiratory effort waveform for two complete respiratory cycles in figure 2a. "Each wave of the waveform is characterized by a negative peak 30 on completion of expiration, a positive peak 35 on completion of inspiration and a turning point 40 which

indicates the onset of inspiration. Each wave of the waveform can therefore be separated into a period of respiratory pause 32, an inspiratory phase 33 and an expiratory phase 34" (col. 5, lines 25-31). Therefore, sensing the respiratory waveform implicitly corresponds to the patient's inspiration duration and the exhalation duration.

Additionally, Testerman et al. delivers a stimulation signal which affects the diaphragm and thus elicits a diaphragm response. Furthermore, such stimulation alters the intrinsic breathing and thus elicits an inspiration and exhalation duration and rate different from the intrinsic inspiration and exhalation duration and rate.

The functional language and introductory statement of intended use of claims 149-150 have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Testerman et al. utilizes a stimulator as claimed by the Applicant, Testerman et al. is therefore capable of being used to deliver a signal to the tissue to elicit a slow elongated inspiration or a fast, short inspiration. In addition nothing prevents Testerman et al. from eliciting these types of breaths. Therefore, the Testerman et al. is capable of administering stimulation to elicit a slow elongated inspiration or a fast, short inspiration.

2. Claims 123-127, 141-142 and 149-158 are rejected under 35 U.S.C. 102(e) as being anticipated by Ignagni et al. (US Patent Publication 20050021102 A1). Ignagni et al. discloses a method of conditioning a diaphragm by delivering electrical stimulation to cause the diaphragm to contract. The "electrical stimulation of the diaphragm can be synchronized with attempts at breathing or breathing made by the patient (e.g., on the patient's own or by the mechanical ventilator). For example, electrical stimulation can be

triggered following the inspiration phase of the breath (i.e., during exhalation) to maximize the contraction during the period when the diaphragm is at its longest length"(page 4, paragraph 38). Therefore, the diaphragm stimulation intrinsic breathing and thus elicits an inspiration and exhalation duration and rate different from the intrinsic inspiration and exhalation duration and rate.

The functional language and introductory statement of intended use of claims 149-150 have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Ignagni et al. utilizes a stimulator as claimed by the Applicant, Ignagni et al. is therefore capable of being used to deliver a signal to the tissue to elicit a slow elongated inspiration or a fast, short inspiration. In addition nothing prevents Ignagni et al. from eliciting these types of breaths. Therefore, the Ignagni et al. is capable of administering stimulation to elicit a slow elongated inspiration or a fast, short inspiration.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALYSSA M. ALTER whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
Art Unit 3762